Pollogen™

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NOV 16 2011

510(K) Summary

apollo™ system

510(k) Number K 111026

Applicant's Name: Pollogen Ltd.
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Binyamina, Israel 30500
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Yoram@qsitemed.com

Trade Name: *apollo*™

Summary Preparation Date: April 14, 2011

Classification: **Name**: Electrosurgical, cutting & coagulation device & accessories
Product Code: GEI
Regulation No: 21 CFR 878.4400
Class: II
Panel: General and Plastic Surgery

Device Description:

The *apollo*™ system delivers RF current into the skin to generate heat through electrical impedance in the dermis and subcutaneous layers. The system consists of:

- Main Unit (includes the Controller)
- Control Panel (User Interface)
- RF Generator
- Three Treatment Applicators
- Foot Switch
- Patient-Controlled Manual Switch

Pollogen™ K111026

The three applicators differ in size and configuration and are indicated for treatment of various size facial areas. The operator can adjust treatment parameters such as the power level and treatment time from the user interface on the Main Unit. The Applicator is applied with low pressure and a rubbing/massaging technique (linear, circular, etc., depending on the area). The applicator should be moved continuously on the skin. No active cooling of the electrodes or the skin is required.

The RF power module provides RF energy to the selected applicator at a frequency of 1 MHz and a maximum output RMS power of 50 watts for applicators No. 1 and 2 and a maximum RMS power of 15 watts for applicator No. 3.

Intended Use Statement:

The ***apollo***™ is a non-invasive device intended for use in Dermatologic and general surgical procedures for the non-invasive treatment of mild to moderate facial wrinkles and rhytides.

Predicate Devices: Substantial equivalence to the following predicate devices is claimed:

Device Name	510k No	Date of Clearance
Venus Concept Ltd. Venus Freeze	**K100586**	Nov 29, 2010
EndyMed Imagine TC Skin Treatment System	**K083461**	Jul 24, 2009

Performance Standards

apollo™ complies with the European Medical Directive 93/42/EEC concerning medical devices (Annex II) and with the following standards:

- ***EN 60601-1*** Medical Electrical Equipment-Part 1: General Requirements for Safety. Collateral Standard: Safety Requirements for Medical Electrical Systems.
- ***IEC 60601-1-2*** Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.
- ***ANSI AAMI 60601-2-2*** - safety of high frequency surgical equipment.

A detailed description appears in **Section 14**.

Summary of Clinical performance data

The safety and efficacy of radiofrequency devices emitting energy with a frequency of 1 MHz and power of up to 50 W is well established in scientific research and clinical studies. Multiple studies with similar systems have shown safety in dermatologic therapy and the devices were cleared by the FDA for therapy of wrinkles and rhytides.

Due to the comprehensive animal and clinical study performed in scientific research and published in the literature, and since the power and frequency of the ***apollo***™ are well within the previously cleared values, Pollogen believes that animal and clinical studies are not required to determine the safety and efficacy of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 16 2011

Pollogen Ltd.
% Qsite
Mr. Yoram Levy
31 Haavoda Street
Binyamina, Israel 30500

Re: K111026
Trade/Device Name: apollo™
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 01, 2011
Received: November 04, 2011

Dear Mr. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Pollogen™

K 111026

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: *apollo*™

Indications for Use: The *apollo*™ is a non-invasive device intended for use in Dermatologic and General Surgical procedures for the non-invasive treatment of mild to moderate facial wrinkles and rhytides.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of General and Plastic Surgery Devices
510(k) Number

Neil R. Ogden for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111026